



REPUBLIC OF KENYA  
**PHARMACY AND POISONS  
BOARD**

Pharmacy & Poisons Board House  
Lenana Road, Nairobi  
P.O BOX 27663-00506, TEL 2716905/6

**Guidelines  
for  
Registration of Premises  
and issuance of  
Wholesale Dealer's  
License**

Edition 1

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# **Guidelines for Registration of Premises and issuance of Wholesale Dealer's License**

This document has been prepared to serve as a guide to applicants regarding the registration of premises and licensing as a wholesale dealer. These guidelines are based on the provisions of the Pharmacy and Poisons

Act, Cap 244 Laws of Kenya and reflect the Pharmacy and Poisons Board's current thinking on the safety, quality and efficacy of medicines. The Board reserves the right to request for any additional information to establish the suitability of the applicant for licensing and may make amendments in keeping with the knowledge which is current at the time of consideration of information which has been submitted in the application

## **FOREWORD**

The Pharmacy and Poisons Board is committed to its mission to ensure the availability of pharmaceutical services in Kenya which satisfy the needs of all for the prevention, diagnosis and treatment of diseases using safe, efficacious, high quality and cost effective pharmaceutical products.

Pursuant to this mission, it is imperative that pharmaceuticals are distributed by highly qualified personnel through outlets that are duly licensed and professionally run. The operations in those premises should at all times be supervised by qualified personnel and the risk of exposing the public to unsafe medicines avoided at all cost. These guidelines have been prepared to provide persons in the pharmaceutical fraternity with a method of assessing eligibility and the process of lawfully operating drug distribution outlets.

The success of this initiative will ultimately depend on the active contribution and cooperation of every stakeholder. I trust that all will strive to uphold the safety of medicines.

DR. SIYOI F.M.  
REGISTRAR.

## **ACKNOWLEDGEMENTS**

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Dr. F. Siyoi  
Dr. I. Mohamed  
Dr. Ochieng W.O.  
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## **1. DEFINITIONS**

“Registered pharmacist “means a person whose name is entered in the register as a pharmacist;

“Enrolled pharmaceutical technologist” means a pharmaceutical technologist whose name appears on the roll of pharmaceutical technologists;

“Registered premises “means premises registered in accordance with section 23 of the Pharmacy and Poisons Act, and where a valid certificate for registration is available/has been issued;

## **2. TYPES OF PREMISES**

Premises are registered as either

- a) Premises for a pharmacist ( for carrying on the business of a pharmacist) or
- b) Premises for Wholesale( for carrying on the business of a pharmacist on wholesale basis only) or
- c) Premises for a pharmaceutical technologist ( for carrying on the business of a pharmaceutical technologist)

## **3. ELIGIBILITY TO SUPERINTEND**

A Pharmacist shall only be eligible to superintend over registered premises if he/ or she holds a valid practice license.

A pharmaceutical technologist shall only be eligible to superintend over premises registered for a pharmaceutical technologist and only if he/ or she holds a valid license to practice as a pharmaceutical technologist

A pharmaceutical technologist shall only be eligible to superintend over premises registered for a pharmaceutical technologist if he/she has worked under supervision of another qualified superintendent (pharmacist or pharmaceutical technologist) for a period of not less than six years from the time of obtaining the diploma in pharmacy.

Any person(s) who wants to apply for registration of premises shall do so in writing and upon completion of the prescribed forms and provision of the documents prescribed in these guidelines or as may be prescribed by the Board.

One person shall only be eligible to superintend over one registered premise.

A reasonable distance shall be maintained between any two registered premises to discourage unfair competitive trade practices.

A body corporate/ limited liability company may apply to operate more than one premise (as branches). However the requirements stipulated under section 21 of the Pharmacy and Poisons Act must be adhered to including that in each set of premises there shall be a different superintendent

pharmacist working under the supervision of the overall responsible company pharmacist.

Where such superintendent is not a shareholder in the company, the pharmacist can formally be appointed in writing and a written acceptance letter will be recognized as legally binding provided the company pharmacist is the majority shareholder having controlling shares in the company.

The board shall be notified in writing at least 30 days prior to any changes affecting the following being implemented:

- a. Change of ownership- includes change in share distribution, change of directors etc
- b. Superintendent/ responsible pharmacist/ pharmaceutical technologist
- c. Change in registered premises i.e. change in location, plot number, building etc.
- d. Nature of business- wholesale/ retail
- e. Change from business of a pharmacist to business of a pharmaceutical technologist and vice versa.
- f. Any other significant changes

#### **4. OWNERSHIP AND BASIC REQUIREMENTS**

In addition to the information and documentation provided by the applicant, the Pharmacy and Poisons Board may conduct or cause to be conducted a search of the records kept by the Registrar of Companies to verify the registered owners of any establishment/business making an application for registration of premises or Wholesale Dealer's License.

##### **4.1. PREMISES FOR PHARMACISTS**

A pharmacist can own the business as either



- i. A sole proprietor or
- ii. A partnership or
- iii. A limited company.

In cases (ii) and (iii) above., the superintendent pharmacist must be the majority shareholder and proof of the same attached in the form of an affidavit for case (ii) or articles and memorandum of association for case(iii).

Any one premise for a pharmacist shall be registered as either retail or wholesale business but NOT as both. Where a person wishes to carry out retail and wholesale business then the person shall lodge an application for registration of different sets of premises and each set must have a designated superintendent.

The premises registration automatically expires on 31<sup>st</sup> day of December in the year it is issued and, if not renewed, the registration shall become void.

#### 4.2. PREMISES FOR PHARMACEUTICAL TECHNOLOGISTS

A pharmaceutical technologist can own the business as either

- i. A sole proprietor or
- ii. A partnership

In case (ii) above, the superintendent pharmaceutical technologist can only be joint owners with other qualified persons namely

- a. Registered pharmacists
- b. Enrolled pharmaceutical technologists

Further, in case (ii) above, the superintendent pharmaceutical technologist must be the majority shareholder and proof of the same attached in the form of an affidavit.

Any one premise for a pharmaceutical technologist will be registered as a retail pharmacy only.

The premises registration automatically expires on 31<sup>st</sup> day of December in the year it is issued and, if not renewed, the registration shall become void.

#### 4.3. PREMISES FOR WHOLESALE

Notwithstanding the requirement for registration of premises, a person intending to carry out the business as a wholesale dealer in pharmaceuticals is further required to apply for and obtain a valid Wholesale Dealers' License. Premises registered for wholesale shall be used solely for that purpose.

Any additional warehouses for storage of pharmaceuticals must be declared by the dealer and will be subject to registration upon confirmation that it meets the minimum requirements for storage of pharmaceuticals.

A pharmaceutical technologist will not be eligible for a Wholesale Dealers' License.

The Wholesale Dealers License automatically expires on 31<sup>st</sup> day of December in the year it is issued.

#### 5. MINIMUM REQUIREMENTS AND STANDARDS OF PRACTICE

The minimum requirements for premises and standards of practice are contained in the Pharmacy and Poisons Board guidelines for Good Wholesaling and Retail Practices for Pharmaceuticals (see separate document).

#### 6. HOW TO MAKE AN APPLICATION FOR REGISTRATION OF PREMISES

An application for registration of premises shall be made in writing and upon completion of the prescribed forms. The

duly completed application forms are to be submitted accompanied by the documents prescribed in these guidelines (see the checklists) or any other documents as may be deemed necessary or as may be prescribed by the Board.

Application forms are available at the Pharmacy and Poisons Board offices along Lenana Road in Nairobi. The forms can be obtained, free of charge, from the Pharmaceutical Inspectorate Department.

The requisite application forms **for retail pharmacy run by a registered pharmacist** are:

- i. *Form 4 (Application for Registration of Premises)*
- ii. *Annexe 1 ( Confidential questionnaire designated for premises to be run by pharmacist)*
- iii. *Form 27(application for annual practice licence) - This is to be filled where the superintendent pharmacist does not yet hold a valid annual practice licence.*

The requisite application forms for **wholesale pharmacy** are:

- i. *Form 4 (Application for Registration of Premises)*
- ii. *Annexes 1 ( Confidential questionnaire designated for premises to be run by pharmacist)*
- iii. *Form 6- Application for a Wholesale Dealer's Licence*
- iv. *Form 27(Application for Annual Practice Licence) - This is to be filled where the superintendent pharmacist does not yet hold a valid annual practice licence.*
- v. *The applicant will specify if, in addition, they intend to carry out the business as importers and or exporters.*

- vi. *A wholesale Dealer SHALL BE required to abide with the Good Distribution Practices guidelines set by the Board. Failure to abide by the guidelines may lead to necessary disciplinary action being taken against the affected person(s).*

The requisite application forms **for retail pharmacy run by an enrolled pharmaceutical technologist** are:

- i. *Form 30 (Application for Registration of Premises for a Pharmaceutical Technologist)*
- ii. *Annexe 2( Confidential questionnaire designated for premises to be run by a pharmaceutical technologist)*
- iii. *Form 29(Application for Licence Practice to Practice as a Pharmaceutical Technologist) - This is to be filled where the superintendent pharmaceutical technologist does not yet hold a valid practice licence.*

The completed application form together with the relevant documents indicated in the checklist should be submitted in person to the address below.

The Registrar,  
Pharmacy & Poisons Board,  
Lenana Road, *(Between the Egyptian Embassy and Lenana Conference Centre)*  
Nairobi

It may alternatively be sent by post to:

The Registrar,  
Pharmacy & Poisons Board  
P.O BOX 27663-00506, Nyayo Stadium,  
Nairobi.

Upon submission of the application documents the applicant shall pay a non- refundable application fees as stipulated below (current fees) or as may be prescribed by the Board.

## **7. CURRENT APPLICATION FEES STRUCTURE**

*Retail Pharmacy (applies to both premises for a pharmacist and premises for a pharmaceutical technologist)*

- |     |                           |            |
|-----|---------------------------|------------|
| i.  | Annual practice licence   | Kshs. 2500 |
| ii. | Premises registration fee | Kshs. 5000 |

*Wholesale Pharmacy*

- |      |                            |             |
|------|----------------------------|-------------|
| i.   | Annual practice licence    | Kshs. 2500  |
| ii.  | Premises registration fee  | Kshs. 5000  |
| iii. | Wholesale dealer’s licence | Kshs. 5000. |

## **8. PROCESSING OF APPLICATIONS**

Upon receipt of the duly filled application forms and documents, the same will be evaluated and the applicant advised in writing on whether the application was successful or not. In conducting the evaluation, the Board may arrange an interview for the applicant (superintendent) by the Practice Committee of the Board. If the interview is successful, an inspection of the proposed company’s premises will be conducted by a pharmaceutical inspector to assess the suitability for the intended business. The inspection report will be presented in the prescribed inspection form.

Having considered all factors and matters relating to the application the Board will either

- a. Issue a certificate of registration of premises under part II of the Pharmacy and Poisons Act, Cap 244 Laws of Kenya; or

- b. Advise the applicant in writing, in case of an unsuccessful application, and clearly state the reason the application was unsuccessful.

In the case of an unsuccessful application, the applicant will be given further opportunity to revise and comply. Where the applicant is able to revise the application and comply with the requirements a licence will be issued; otherwise the premises shall remain unregistered and the file will be closed after about 6 months from the date of initial application.

*Nothing in these guidelines shall make it lawful to carry out the business in premises which are not registered even when an application is under process but the license has not yet been issued.*

## **9. VALIDITY OF REGISTRATION CERTIFICATE AND/ OR WHOLESALE DEALER'S LICENCE**

The Certificate for Registration of Premises (Form 33) expires on the 31<sup>st</sup> day of December of the year it is issued. The Wholesale Dealer's Licence (Form 7) expires on the 31<sup>st</sup> day of December of the year it is issued. The Certificate for Registration of Premises for a Pharmaceutical Technologist's Practice (Form 31) expires on the 31<sup>st</sup> day of December of the year it is issued.

The above expiry dates will apply irrespective of the actual date of issue of the license in question.

## **10. RENEWAL OF LICENSES**

All licenses issued by the Board and expiring on the 31<sup>st</sup> day of December of the year it is issued will be renewable annually. Application for renewal of licences will be made to the Board in writing by filling the forms stipulated in part 6 above. However, for purposes of renewal, it shall not

be necessary to fill the annexes except in a situation where there are changes in details that may require variation of license.

Notwithstanding licenses having been issued the previous year, the application for renewal shall be evaluated every time and the Board shall not be obliged to renew the licenses except for applications which as per the prevailing conditions at the time of application still meet the requirements. Premises which, after re-assessment, are deemed to have become unsuitable for carrying on the business will not have their registration renewed and the previous one would automatically become void.

The requisite forms for renewal are to be filled and application fees paid beginning October and not later than 31<sup>st</sup> December every year in order to facilitate timely processing of the licenses.

#### **11. PENALTY FOR LATE RENEWAL:**

Any application for renewal of licenses that is lodged later than 31<sup>st</sup> December will attract a penalty for late application and this will be in the form of a percentage of the standard application fees as may be prescribed by the Board. Currently the penalty is 10% and is levied on a monthly incremental basis from January onwards.





## **CHECKLIST 1**

*(Designated for premises to be run by pharmacist)*

Please submit this checklist with the following documents in person or via post. If you have answered “no” to any question, Please provide a written explanation.

### **Have you submitted?**

1. *A completed application form?*
2. *Copies of academic certificate/s of superintendent pharmacist?*
3. *A copy of B.Pharm/Bsc Pharmacy Degree certificate must be included.*
4. *A Copy of the superintendent pharmacist’s Certificate of registration as a pharmacist*
5. *For Limited companies*
  - i. *A Copy of Certificate of incorporation*
  - ii. *Articles of association and Memorandum of association*
  - iii. *An Affidavit?*

*For partnerships*

- i. *A Copy of Certificate of registration of company name (Form BN/3) from the Registrar of companies, Attorney General’s office?*
- ii. *An affidavit?*

*For sole proprietorship: a copy of Certificate of registration of company name (Form BN/3) from the Registrar of companies, Attorney General’s office?*

6. *Superintendent pharmacist’s resignation letter to last employer?*
7. *Letter of appointment of Superintendent Pharmacist by the company applying for registration?*
8. *Clearance by a professional body, Kenya?*
9. *Two coloured passport size photographs.*
10. *Floor plan of Dispensary?*
11. *Floor plan of Dispensing Room?*

12. *Floor plan of Consultation room?*

**CHECKLIST 2**

*(Designated for premises to be run by pharmaceutical technologist)*

Please submit this checklist with the following documents in person or via post. If you have answered “no” to any question, Please provide a written explanation.

**Have you submitted?**

1. *A completed application form?*
2. *Copies of academic certificate/s of superintendent pharmaceutical technologist?*  
*A copy of Diploma certificate in Pharmacy must be included.*
3. *A Copy of Enrolment Certificate by Pharmacy & Poisons Board, Kenya, for the superintendent pharmaceutical technologist?*

*For sole proprietorship*

- i. *A Copy of Certificate of registration of company name (Form BN/3) from the Registrar of companies, Attorney General’s office?*

**Or**

*For partnerships*

- i. *A Copy of Certificate of registration of company name (Form BN/3) from the Registrar of companies, Attorney General’s office?*
  - ii. *An affidavit?*
4. *Superintendent pharmaceutical technologist’s resignation letter to last employer?*
  5. *Letter of appointment of Superintendent Pharmaceutical technologist by the company applying for registration?*
  6. *Clearance by a professional body, Kenya?*
  7. *Two coloured passport size photographs.*
  8. *Floor plan of Dispensary?*
  9. *Floor plan of Dispensing Room?*
  10. *Floor plan of Consultation room?*

## **CHECKLIST 2**

*(Designated for premises to be run by pharmaceutical technologist)*

Please submit this checklist with the following documents in person or via post. If you have answered “no” to any question, Please provide a written explanation.

### **Have you submitted?**

11. *A completed application form?*
12. *Copies of academic certificate/s of superintendent pharmaceutical technologist?*  
*A copy of Diploma certificate in Pharmacy must be included.*
13. *A Copy of Enrolment Certificate by Pharmacy & Poisons Board, Kenya, for the superintendent pharmaceutical technologist?*  
*For sole proprietorship*
  - ii. *A Copy of Certificate of registration of company name (Form BN/3) from the Registrar of companies, Attorney General’s office?*

**Or**

*For partnerships*
  - iii. *A Copy of Certificate of registration of company name (Form BN/3) from the Registrar of companies, Attorney General’s office?*
  - iv. *An affidavit?*
14. *Superintendent pharmaceutical technologist’s resignation letter to last employer?*
15. *Letter of appointment of Superintendent Pharmaceutical technologist by the company applying for registration?*
16. *Clearance by a professional body, Kenya?*
17. *Two coloured passport size photographs.*
18. *Floor plan of Dispensary?*
19. *Floor plan of Dispensing Room?*

20. *Floor plan of Consultation room?*